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Prevalence and predictors of type II diabetes mellitus in heart failure patients with reduced left ventricular ejection fraction, Madinah, Saudi Arabia

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ABSTRACT

Background: Heart Failure (HF) occurs more commonly in patients with type II Diabetes Mellitus (DM). Conversely, recent publications suggesting that the reverse is also true. Many mechanisms have been suggested, including sympathetic nervous system overactivity. Also, neurohormonal activation leads to an increase in the levels of catecholamines and cortisol which inhibit pancreatic insulin secretion and stimulate hepatic gluconeogenesis and glycogenolysis. **Methods:** This is a cross-sectional study conducted at Madinah cardiac center involving HF patients with reduced left ventricular ejection fraction (HFrEF) during the period from 1-March-2011 to 20-June-2019. Patients were divided into two groups based on the presence or absence of type II DM. **Results:** Out of 1607 patients included in the analysis, 1078 (67.1%) were males, 127 (7.9%) had myocardial infarction (MI), 356 (22.2%) valvular heart disease, 597 (37.1%) Coronary Artery Diseases (CADs), 146 (9.1%) underwent percutaneous coronary interventions and 95 (5.9%) underwent coronary artery bypass grafting. 825 (51.3%) were hypertensive, 835 (52.0%) were anemic, 289 (18.0%) were smokers, and 629 (39.1%) had stage 3 chronic kidney diseases. About 56.1% of HF patients were diabetic. Multivariate analysis showed that older age [OR, 1.02; 95% CI, 1.01-1.03; p<0.001], presence of Hypertension (HTN) [OR, 4.06; 95% CI, 3.20-5.16; p<0.001], anemia [OR, 1.68; 95% CI, 1.33-2.13; p<0.001] or CADs [OR, 1.78-2.28; 95% CI, 1.01-1.03; p<0.001] were the independent predictors of type II DM. **Conclusions:** About 56.1% of HFrEF patients were diabetic. Older age, presence of HTN, anemia, or CADs were the independent predictors of type II DM.

Keywords: Heart Failure, Diabetes Mellitus, Madinah cardiac center

1. INTRODUCTION

Heart Failure (HF) and Diabetes Mellitus (DM) frequently co-exist. DM has been associated with changes in cardiac function and structure (Kannel et al.,



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1994). The presence of DM leads to an increase in atherosclerosis rate, and the existence of specific diabetic cardiomyopathy has been suggested (Sánchez-Torrijos et al., 2007). HF occurs more commonly in patients with DM than in those with normal glucose metabolism (AbuRuz, 2015). Cardiovascular health study found that HF occurred in 31% and 26% of participants with and without type II DM, respectively (Roy et al., 2011). Conversely, recent several publications suggesting that the reverse is also true, i.e., that HF leads to type II DM (Guglin et al., 2014). Large Danish cohort study found that HF is also a risk factor for type II DM. It showed that nondiabetic patients who developed HF as a result of ischemic cardiomyopathy were at a higher risk of new onset type II DM, and the risk was proportionate to the severity of HF (Iribarren et al., 2001).

Currently, the mechanisms proposed for the association of HF with type IIDM are unclear, but there are many possible explanations. Neurohormonal activation which typically presents in HF leads to an increase in the levels of catecholamines and cortisol and increases the blood glucose level. Also, elevated catecholamines can increase insulin resistance and this seems to reduce the release of insulin from the pancreas. Sympathetic nervous system overactivity stimulates glycogenolysis and gluconeogenesis and therefore increases glucose production in the liver (Swan et al., 1997). Another potential mechanism connecting the two conditions is a low-grade chronic inflammation with activation of multiple factors including, but not limited to, interleukins and tumor necrosis factor α , characteristic for HF as well as DM. Insulin resistance appears to progress with the increasing severity of HF (Ement, 2019).

The presence of type II DM in HF patients associated with increasing the HF symptoms and decreasing the functional capacity (Sánchez-Torrijos et al., 2007). Whereas the data on the relation between HF and the rate of development of type II DM are widely available, there is no published evidence regarding the prevalence and predictors of type II DM among HF patients in Saudi Arabia. Accordingly, this is the first study to demonstrate the prevalence and predictors of type IIDM in HF patients with reduced left ventricular Ejection Fraction (HFrEF). Such data are novel and may be of value in predicting those with a high risk of type II DM and therefore help in improving the preventative measures to reduce the incidence of type II DM in such patients, if applicable.

2. MATERIALS AND METHODS

Study Design, Study Setting, and Study Period

This is a cross-sectional study conducted at Madinah cardiac center involving patients with HFrEF registered in the Health Management Information System (HMIS) database during the period from 1-March-2011 to 20-June-2019.

Study Population

We reviewed the electronic medical records from the HMIS. A total of 2683 patients were identified to having a documented clinical diagnosis of HFrEF which was defined as left ventricular ejection fraction $\leq 40\%$ as determined by echocardiography. Patients with type II DM or with a clinical history or laboratory findings consistent with the diagnosis of type II DM before the onset of HF were excluded. Age less than 18 years old and pregnant females were set as an exclusion criterion as well. Of the remaining 1656 patients, we excluded 49 patients with incomplete data, yielding 1607 patients for analysis (Figure 1).

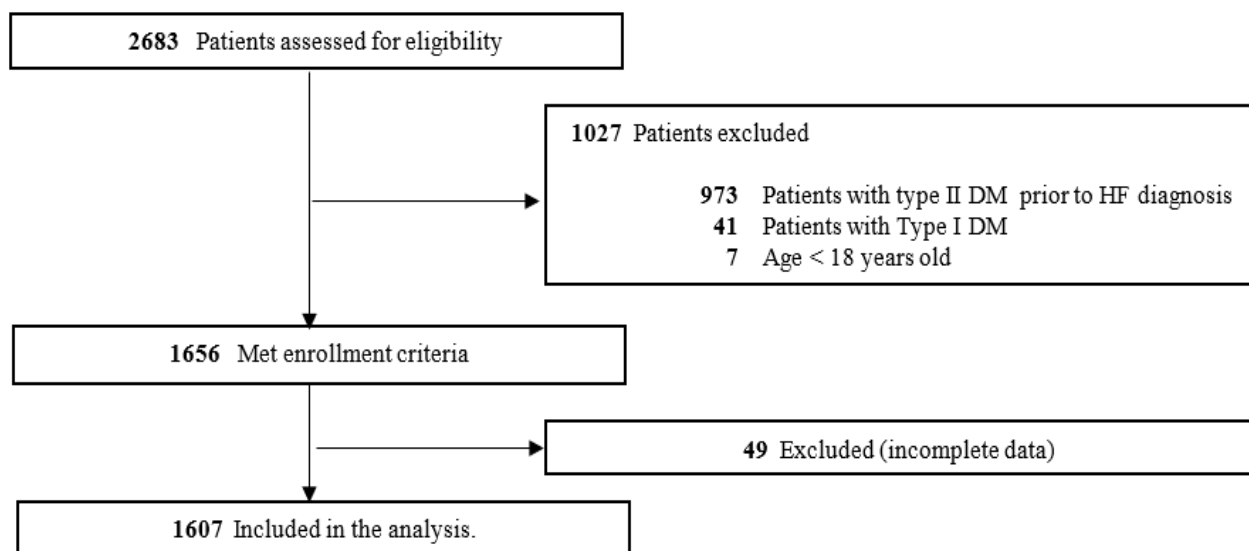


Figure 1 Flow chart of the study population

Measurements

Patients were considered to have type II DM based on serum Hemoglobin A1c (HbA1c) $\geq 6.5\%$ or have at least one for the diagnostic criteria for type II DM as the following: two readings of fasting plasma glucose ≥ 7 mmol/l [126 mg/dl], 2-hours oral glucose tolerance test or random blood glucose ≥ 11.1 mmol/l [200 mg/dl] along with diabetic symptoms (Care, and Suppl., 2018). Glomerular Filtration Rate (GFR) was estimated depending on the equation made by the chronic kidney disease epidemiology collaboration as the following: $eGFR = 141 \times \min(S_{cr} / \kappa, 1)^{\alpha} \times \max(S_{cr} / \kappa, 1)^{-1.209} \times 0.993^{Age} \times 1.018$ [if female] $\times 1.159$ [if black] where: S_{cr} is serum creatinine in mg/dL, κ is 0.7 for females and 0.9 for males, α is -0.329 for females and -0.411 for males (Stevens et al., 2011). All patients were divided according to the current national kidney foundation kidney disease outcomes quality initiative recommendations into five renal function categories with eGFR (mL/min/ 1.73 m²): Stage I (eGFR ≥ 90 , normal function), Stage II (eGFR 60–89, mild dysfunction), Stage III (eGFR 30–59, moderate dysfunction), Stage IV (eGFR 15–29, severe dysfunction) and Stage V (eGFR <15 , end stage renal disease) (Löfman et al., 2016). Anemia was defined as Hemoglobin (Hb) level <13 g/dl and <12 g/dl in males and females respectively, according to the world health organization's criteria for anemia (Alraheili et al., 2020).

Ethical Approval

The research ethics committee of Madinah cardiac center approved this study protocol (approval number: IRB00010413). All study parts were conforming to the declaration of Helsinki Ethical Principles for medical research involving human subjects as revised in 1975.

Statistical Analysis

Data were analyzed using the Statistical Package for Social Science software version 23. Continuous data were presented as mean \pm Standard Deviation (SD) as they were normally distributed when tested by the Shapiro-Wilk test, while the categorical data were presented as frequencies and percentages. Baseline demographic and clinical variables were compared between two groups by using the Pearson chi-squared test for categorical variables. To assess whether the continuous variables differed among the study two groups, we used the independent sample t-test. The predictors of type II DM were determined by using binary logistic regression. P-value was considered significant if it is ≤ 0.05 .

3. RESULTS

Out of 1607 patients included in the analysis, 1078 (67.1%) were males, 127 (7.9%) had a history of Myocardial Infarction (MI), 356 (22.2%) had valvular heart disease, 597 (37.1%) had Coronary Artery Diseases (CADs), 146 (9.1%) underwent Percutaneous Coronary Interventions (PCI) and 95 (5.9%) underwent Coronary Artery Bypass Grafting (CABG). 825 (51.3%) were hypertensive, 835 (52.0%) were anemic, 289 (18.0%) were smokers, and 629 (39.1%) had stage 3 Chronic Kidney Diseases (CKDs). 1418 (88.2%) were on angiotensin converting enzyme inhibitors and 994 (61.9%) were on aspirin (Table 1).

Table 1 Sociodemographic and clinical characteristics of the study population

Variables	Number (n=1607)	(%)
Gender		
Female	529	(32.9)
Male	1078	(67.1)
Cardiac History		
Myocardial Infarction	127	(7.9)
Atrial Fibrillation	215	(13.4)
Arrhythmias	98	(6.1)
Valvular Heart Disease	356	(22.2)
Coronary Artery Diseases	597	(37.1)
Percutaneous Coronary Interventions	146	(9.1)
Coronary Artery Bypass Grafting	95	(5.9)
Cardiac Device	98	(6.1)
Cardiac Arrest	52	(3.2)
Noncardiac History		
Current Smoker	289	(18.0)
Anemia	835	(52.0)

Hypertension	825	(51.3)
Type II Diabetes Mellitus	902	(56.1)
Stroke	103	(6.4)
Chronic Kidney Diseases		
Stage 1 (eGFR > 90 mL/min)	242	(15.1)
Stage 2 (eGFR 60-89 mL/min)	501	(31.2)
Stage 3 (eGFR 30-59 mL/min)	629	(39.1)
Stage 4 (eGFR 15-29 mL/min)	182	(11.3)
ESRD (eGFR < 15 mL/min)	53	(3.3)
Medications		
Aspirin	994	(61.9)
Clopidogrel	229	(14.3)
Angiotensin Converting Enzyme Inhibitors	1418	(88.2)
Beta Blockers	272	(16.9)
Digoxin	565	(35.2)
Anticoagulants	99	(6.2)
Diuretics	530	(33.0)
Statin	591	(36.8)
Ferrous sulfate	631	(39.3)
eGFR; estimated Glomerular Filtration Rate, ESRD; End-Stage Renal Disease		

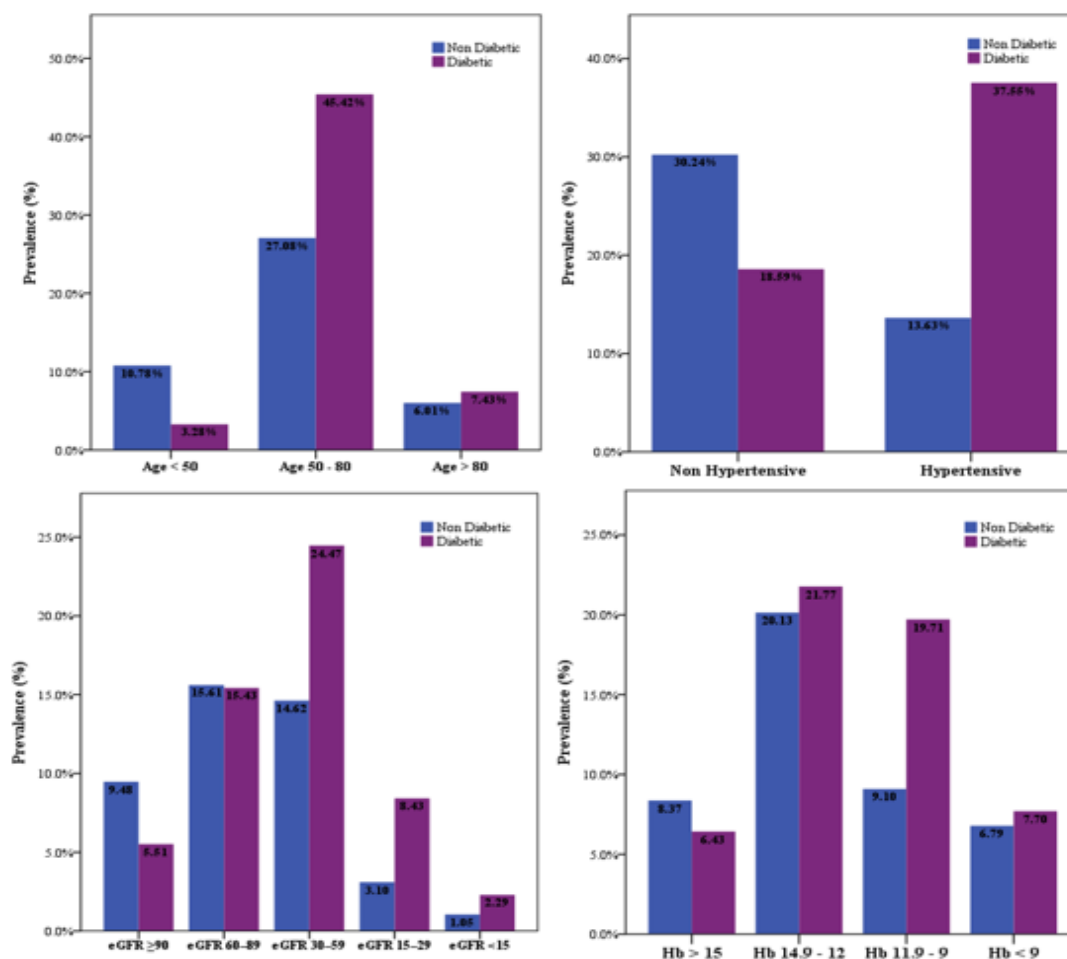


Figure 2 Prevalence of type II DM regarding to; (A) Age categories, (B) HTN, (C) CKDs stages, (D) Hb level

About 56.1% of patients were diabetic. Diabetic patients were significantly older. Mean \pm SD of age was 68 ± 11 years in diabetic patients compared to 63 ± 11 years in nondiabetic patients [$p < 0.001$]. Diabetic patients were significantly females [$p < 0.001$], had a history of atrial fibrillation [$p < 0.001$], valvular heart diseases [$p < 0.001$], CADs [$p < 0.001$], arrhythmias [$p = 0.002$], Hypertension (HTN) [$p < 0.001$], anemia [$p < 0.001$], stroke [$p = 0.012$], CKDs [$p = 0.020$], underwent PCI [$p < 0.001$], or CABG [$p = 0.013$]. There was no significant association in history of MI or smoking. (Figure 2) showed the prevalence of type II DM regarding to age categories, HTN, CKDs stages, and Hb level.

Table 2 Baseline characteristic stratified by presence or absences of type II DM (n=1607)

Clinical Variable	Diabetic (n=902) (56.1%)		Non Diabetic (n=705) (43.9%)		OR (95% CI)		P value
	Number (%) / Mean ± SD						
Age	68±11		63±17				<0.001
Gender							
Female	335	(63.3)	194	(36.7)	1.556	(1.257-1.927)	<0.001
Male	567	(52.6)	511	(47.4)			
Cardiac History							
Myocardial Infarction	70	(55.1)	57	(44.9)	0.956	(0.664-1.377)	0.811
Atrial Fibrillation	89	(41.4)	126	(58.6)	0.503	(0.376-0.673)	<0.001
Arrhythmias	40	(40.8)	58	(59.2)	0.518	(0.342-0.784)	0.002
Valvular Heart Disease	158	(44.4)	198	(55.6)	0.544	(0.429-0.690)	<0.001
Coronary Artery Diseases	395	(66.2)	202	(33.8)	1.940	(1.573-2.393)	<0.001
PCI	102	69.9)	44	(30.1)	1.915	(1.325-2.768)	<0.001
CABG	65	(68.4)	30	(31.6)	1.747	(1.120-2.725)	0.013
Cardiac Device	45	(45.9)	53	(54.1)	0.646	(0.429-0.973)	0.036
Cardiac Arrest	31	(59.6)	21	(40.4)	1.159	(0.660-2.035)	0.607
Noncardiac History							
Current Smoker	149	(51.6)	140	(48.4)	0.799	(0.619-1.031)	0.084
Anemia	525	(62.9)	310	(37.1)	1.774	(1.454-2.165)	<0.001
Hypertension	606	(73.5)	219	(26.5)	4.543	(3.677-5.614)	<0.001
Stroke	70	(68.0)	33	(32.0)	1.713	(1.119-2.624)	0.012
Chronic Kidney Diseases							
Stage 1 (eGFR > 90 mL/min)	148	(61.2)	94	(38.8)			0.020
Stage 2 (eGFR 60-89 mL/min)	288	(57.5)	213	(42.5)			
Stage 3 (eGFR 30-59 mL/min)	356	(56.6)	273	(43.4)			
Stage 4 (eGFR 15-29 mL/min)	83	(45.6)	99	(54.4)			
ESRD (eGFR < 15 mL/min)	27	(50.9)	26	(49.1)			
Medications							
Aspirin	527	(53.0)	467	(47.0)	0.716	(0.584-0.879)	<0.001
Clopidogrel	161	(70.3)	68	(29.7)	2.035	(1.504-2.755)	<0.001
ACEIs	805	(56.8)	613	(43.2)	1.246	(0.919-1.688)	0.156
Beta Blockers	156	(57.4)	116	(42.6)	1.062	(0.816-1.382)	0.655
Digoxin	257	(45.5)	308	(54.5)	0.514	(0.417-0.632)	<0.001
Anticoagulants	46	(46.5)	53	(53.5)	0.661	(0.440-0.994)	0.045
Diuretics	230	(43.4)	300	(56.6)	0.462	(0.374-0.571)	<0.001

Statin	285	(48.2)	306	(51.8)	0.602	(0.491-0.739)	<0.001
Ferrous sulfate	310	(49.1)	321	(50.9)	0.626	(0.512-0.767)	<0.001
Hospitalization History							
Number of hospitalizations	1.63 ± 1.193		1.79 ± 1.660				0.098
Total length stays	11.86 ± 20.415		13.61 ± 28.062				0.103
Death	46	(22.8)	156	(77.2)	0.189	(0.134-0.267)	<0.001
PCI; Percutaneous Coronary Interventions, CABG; Coronary Artery Bypass Grafting, eGFR; estimated Glomerular Filtration Rate, ESRD; End-Stage Renal Disease ACEI; Angiotensin Converting Enzyme Inhibitors							

Medical therapy using differed between diabetic and nondiabetic patients. Using aspirin, digoxin, diuretics, statins, and ferrous sulfate was markedly lower in diabetic patients [$p<0.000$]. Also, clopidogrel use was higher in diabetic patients compared to nondiabetic patients. Clopidogrel was used in 161 (70.3%) and 68 (29.7%) in diabetic and nondiabetic patients, respectively [$p<0.001$]. Detailed clinical characteristics are shown in (Table 2).

Mean Hb level was 12.22±2.18 g/dl in diabetic patients compared to 13.10±2.21 g/dl in nondiabetic patients [$p<0.001$]. Diabetic patients exhibited significantly worsening kidney function tests. Mean eGFR was 56.78±24.87 mL/min in diabetic patients compared to 60.09±33.49 mL/min in nondiabetic patients [$p<0.001$]. Higher levels of creatinine and blood urea nitrogen were also observed in diabetic patients. Detailed laboratory data are shown in (Table 3).

Table 3 Continuous characteristics of the study population stratified by presence or absences of type II DM

Variables	Diabetic (n=902) (56.1%)	Non Diabetic (n=705) (43.9%)	P value
	Mean ± SD		
Complete Blood Count			
Hemoglobin (g/dl)	12.22±2.18	13.10±2.21	<0.001
HCT%	37.19±6.19	39.89±6.10	<0.001
RBC ×10 ¹² /μL	4.36±0.81	4.60±0.75	<0.001
MCV fL	85.96±7.01	87.10±8.23	0.170
WBC ×10 ³ /μL	10.02±5.60	9.43±6.00	0.238
Platelet Count ×10 ³ /μL	266.87±103.34	257.73±107.64	0.132
Kidney Function Test			
eGFR (mL/min)	56.78±24.87	60.09±33.49	0.081
Creatinine (μmol/L)	145.38±93.67	130.12±64.30	0.002
BUN (mmol/L)	11.02±8.19	9.92±6.59	0.005
Sodium (mEq/L)	135.72±6.17	137.61±8.87	<0.001
Troponin (mcg/L)	3.33±9.80	4.36±11.03	0.110
Lipid Profile			
LDL (mmol/L)	2.23±1.02	2.30±1.09	0.036
HDL (mmol/L)	0.96±0.47	0.96±0.39	0.707
Triglycerides (mmol/L)	1.22±0.67	1.25±0.71	0.691
Total cholesterol (mmol/L)	3.74±1.25	3.84±1.33	0.121
HCT%; Hematocrit, RBC; Red Blood Cells, MCV; Mean Corpuscular Volume, WBC; White Blood Cells, eGFR; estimated Glomerular Filtration Rate, BUN; Blood Urea Nitrogen, LDL; Low Density Lipoprotein, HDL; High Density Lipoprotein.			

Multivariate analysis showed that older age [OR, 1.02; 95% CI, 1.01-1.03; $p<0.001$], history of HTN [OR, 4.06; 95% CI, 3.20-5.16; $p<0.001$], presence of anemia [OR, 1.68; 95% CI, 1.33-2.13; $p<0.001$] or CADs [OR, 1.78-2.28; 95% CI, 1.01-1.03; $p<0.001$] were the independent predictors of type II DM (Table 4).

Table 4 Predictors of type II DM in HFrEF patients

Variables	Sig	Exp(B)	95%C.I.for EXP(B)	
			Lower	Upper
Age	<0.001	1.017	1.008	1.025
Female	0.206	1.180	0.913	1.527
Coronary Artery Diseases	<0.001	1.784	1.395	2.282
Percutaneous Coronary Intervention	0.198	1.333	0.860	2.067
Coronary Artery Bypass Grafting	0.390	1.250	0.752	2.078
Hypertension	<0.001	4.062	3.196	5.162
Stroke	0.544	1.167	0.708	1.923
Anemia	<0.001	1.683	1.331	2.128
Renal dysfunction	0.926	1.011	0.796	1.285
Clopidogrel	0.114	1.321	0.936	1.866

4. DISCUSSION

In this study, we demonstrated the prevalence and predictors of type II DM among HFrEF patients in Saudi Arabia. We found that about 56.1% of HFrEF patients were diabetic. Past study demonstrated that HF is associated with a 2-fold increase in the risk of new-onset type II DM within 3 or 4 years, compared to individuals without prior HF. It has been reported that not only type II DM is a risk factor for HF; HF is also a risk factor for type II DM (Guglin et al., 2014). However, relatively few studies have addressed the issue of HF potentially precipitating the development of DM. Advanced HF leads to increased insulin resistance, characterized by fasting and stimulated hyperinsulinemia, which is a major risk factor for the development of diabetes (Das et al., 2004). Also, patients with HF often have reduced physical activity, which may increase the risk of diabetes (Roy et al., 2011). MacDonald et al., (2008) reported that the 3 years incidence of new onset type II DM was 28.8% in the elderly HF patients, compared with 18.3% in matched controls without HF.

Previous studies found that hyperglycemic state and insulin resistance are common among nondiabetic HF patients. From et al, (2006) estimated the prevalence of type II DM in HF patients varies from 4% to 35%. It was also mentioned in the Preiss et al, (2009) study that the prevalence of type II DM in patients with HF is substantial between 20% to 30%. However, Zareini et al, (2019) study reported that the annual incidence of new onset diabetes was approximately 2% in the first year after diagnosis of HF and rising to around 3% after 5 years of HF duration. In CHARM program, 7.4% of patients with HF developed type II DM over a median of 3 years. Similarly, a cohort study done on HF patients over a median period of 2 years, reported that 7.8% of the 1,620 patients developed diabetes during follow up (Yusuf et al., 2005).

In a large Danish cohort study, which followed a nondiabetic population after acute MI. Patients who developed HF were at a higher risk of developed a new onset type II DM. It showed that HF is a risk factor for new onset DM (Demant et al., 2014). Another study reported the prevalence of type II DM in individuals with left ventricular systolic dysfunction varies from 6-25%, and 12-30% in symptomatic HF patients. It was also reported that in hospitalized HF patients, the prevalence of type II DM is greater, up to 40% (Dries et al., 2001). Amato et al, (1997) reported that HF is an insulin resistant state which constitutes the main risk factor for the development of type II DM. In 1339 elderly subjects, a total of 29.6% of HF patients had type II DM. In the Bezafibrate infarction prevention study, the incidence of type II DM in those without HF over a mean of 7 years was 13%, increasing to 15% and 20% in New York Heart Association (NYHA) class II and III, respectively. It also showed that nondiabetic patients in NYHA class III and IV had higher glucose and insulin levels than patients in NYHA class I or II (Tenenbaum et al., 2003).

The current study found that older age, presence of HTN, anemia, or CAD were the independent predictors of type II DM among HFrEF patients. Data from the previous studies showed older age, male gender, elevated body mass index, history of smoking, higher systolic blood pressure, lower left ventricular ejection fraction, longer duration of HF, higher NYHA functional class, elevated blood glucose level, abnormal HbA1c, using of diuretics, or lipid-lowering therapy were the predictors of incident type II DM among HF patients (Sud et al., 2015; Schmiegelow et al., 2011; Gustafsson et al., 2004). In a community-based cohort study of individuals with HF, they found a high prevalence of type II DM particularly among the older age group (Suskin et al., 2000). However, a study done on 104,522 HF patients found that 8164 patients (10%) developed new-onset diabetes during a mean follow-up of 4 years and were slightly younger than patients without diabetes (70 vs. 74 and 77, respectively) (Zareini et al., 2019). The presence of CADs was found to be a predicate of type II DM in HF patients. This association may reflect either insulin

resistance or underlying lipid abnormalities, which may predict diabetes (Elliott and Meyer, 2007). Furthermore, there are powerful data from the field of HTN showing an increased incidence of diabetes by multiple mechanisms (Vermes et al., 2003; Elliott and Meyer, 2007).

5. CONCLUSIONS

Hyperglycemic state and insulin resistance are common among HF patients due to neurohormonal activation which typically present in HF. About 56.1% of HFREF patients were diabetic. Older age, presence of hypertension, anemia, or coronary artery diseases were the independent predictors of type II DM.

Informed consent

Written and oral informed consent was obtained from all individual participants included in the study.

Ethical approval

The research ethics committee of Madinah cardiac center approved this study protocol (approval number: IRB00010413).

Author's contributions

Raneem Alraheili conducted research, designed, and conceived the study, provided research materials, and collected and organized data, analyzed the data, wrote initial and final draft of article. Yousef Al-Alawiconceived and designed the study, provided supervision and logistic support. Bayan Al-Alawi collected and organized the data and wrote initial draft. Amjad Karam designed figures, wrote initial and final draft of article. Mohammad Manquedesigned tables, organized, and interpreted the data. All authors have critically reviewed and approved the final draft and are responsible for the content and similarity index of the manuscript.

Conflict of interest

The authors have no conflict of interest to declare.

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Data and materials availability

All data associated with this study are present in the paper.

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